

R E M A R K S

The feature of a sodium salt added to claim 1 is supported by the paragraph bridging pages 4 and 5 of the specification.

Claim 3 was editorially revised.

New claims 4 to 7 and 9 to 12 recite features of claim 1.

New claims 8 and 13 are supported by the paragraph bridging pages 4 and 5 of the specification.

New claims 14 and 20 are supported in the specification on page 7, lines 8 to 11 and by original claim 2.

New claims 15 to 17 are supported by the last paragraph on page 7 of the specification.

New claim 18 is supported by the last paragraph on page 7 of the specification and by Tables 1 and 2 on page 12 of the specification.

New claim 19 recites features of claim 3.

New claim 21 recites features that are supported by original claim 3.

New claim 22, which recites "bactericidal effective amounts", is supported in the specification on page 7, last paragraph.

Claim 2 was objected to under 37 CFR 1.75(c) as being of improper independent form for failing to further limit the subject matter of the claim it depends on for the reasons indicated in Item No. 4 beginning at the middle of page 2 of the Office Action.

Claim 2 was canceled hereinabove and was replaced by new claims 14 and 20.

Claims 1 and 2 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 to 4 and 13 over USP 6,329,011 to Oita in view of Garcia-Olmedo et al. USP 5,446,127 for the reasons set forth in Item No. 5 on pages 3 and 4 of the Office Action.

Claims 1 to 4 and 13 of Oita relate to the invention pointed out by the Examiner, namely a composition containing only thionin. As admitted at the top of page 4 of the Office Action, Oita differs from the instant claimed invention because EDTA and EDTA salts are not part of the claimed composition of Oita. Oita thus does not mention a combination of thionin and EDTA.

According to Garcia-Olmedo et al., EDTA (as a metal chelater) is added to a buffer during the procedure when thionin is extracted from a plant to prevent inactivation of extracted thionin. However, after extraction, said EDTA is removed by

centrifugation and HPLC of the extract to obtain purified thionin. At least part of any EDTA contained in the pellet would be removed during centrifugation (see Example 2 in column 16, lines 25 to 28 of Garcia-Olmedo et al.). The above would be clear to one of ordinary skill in the art. In the antibacterial experiment in Garcia-Olmedo et al., only purified thionin was used, without the addition of EDTA.

Thus, it is respectfully submitted that even in consideration of Garcia-Olmedo et al., there would be no motivation to use the thionin in Oita in combination with EDTA.

Claims 1 to 3 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 to 3 of copending application Serial No. 09/802,270, which corresponds to US Patent Application Publication 2002/0058696 by Nagai and Oita (hereinafter referred to as "Nagai et al."), in view of Garcia-Olmedo et al. USP 5,446,1276 for the reasons set forth in Item No. 6 on pages 4 and 5 of the Office Action.

It is noted that U.S. Patent Application Publication 2002/0058696 issued as USP 6,429,225.

Nagai et al. use EDTA or a metal salt thereof. As the Examiner confirmed, there is no description in Nagai et al. for the co-use of thionin. The Nagai et al. patent is specifically

directed to inhibiting the proliferation of *Helicobacter pylori* by EDTA or its metal salt, and no inhibitory effect against another microorganism is confirmed therein.

In Garcia-Olmedo et al., the reason why EDTA is used is to prevent inactivation of said thionin in the extraction thereof. But as aforementioned, EDTA is removed, such as by HPLC in the course of the purification of thionin. Garcia-Olmedo et al. indicated only the inhibition of proliferation of a specific plant pathogen. It is respectfully submitted that it would be not possible or quite difficult to inhibit proliferation of most microorganism only by thionin. This is clear from the results of Table 1 at the middle of page 12 of the present specification. Specifically, a very high concentration of thionin would be expected to be required to combat food poisoning bacteria or, otherwise, a desirable effect would not be obtained.

Under the above circumstances, it was a discovery according to the present invention to obtain an antibactericidal effect at a low concentration of thionin by a combination of thionin and EDTA, which is not taught or suggested by the references. Therefore, the presently claimed invention is entirely different from the cited references.

In view of the above, withdrawal of the two double patenting rejections is respectfully requested.

Claims 1 and 2 were rejected under 35 USC 102 as being anticipated by Garcia-Olmedo et al. USP 5,446,127 for the reasons set forth in Item No. 8 beginning at the bottom of page 5 and continuing to the top of page 6 of the Office Action.

As discussed above, in Garcia-Olmedo et al., EDTA is used to extract thionin from a plant and EDTA is removed by HPLC in the purification of thionin. So in Garcia-Olmedo et al., an antibacterial experiment was carried out with the use of only thionin, without containing EDTA. In other words, Garcia-Olmedo et al. fail to disclose a bactericidal composition containing both thionin and EDTA. Even in the portion of the reference pointed out by the Examiner, a bactericidal composition of the presently claimed invention was not described.

In view of the above, withdrawal of the 35 USC 102 rejection is respectfully requested.

Claims 1 to 3 were rejected under 35 USC 103 as being obvious over Lawyer et al. USP 6,042,848 in view of Garcia-Olmedo et al. USP 5,446,127 for the reasons set forth in Item No. 10 beginning at the bottom of page 6 and continuing to the top of page 8 of the Office Action.

It was admitted in the Office Action that Lawyer et al. do not specifically identify thionins as an alpha-type thionin or a beta-type thionin.

Although Lawyer et al. teach that an antimicrobial activity of antimicrobial of many peptides, one of which being thionin, is maintained and enhanced by an ion of copper, Lawyer et al. do not mention a composition combining both thionin and EDTA. Copper EDTA was exemplified as one of approximately sixty copper salts in column 6, lines 3 to 21 of Lawyer et al. Applicants have informed the undersigned that it is, however, clear that the above-described activity in Lawyer et al. is based on an ion of copper, not due to EDTA. Further, no example of using copper EDTA was described in Lawyer et al.

The content of the Garcia-Olmedo et al. patent was discussed above. Garcia-Olmedo et al. describe the use of EDTA only in the extraction of thionin to prevent inactivation of thionin by a heavy metal ion, and no EDTA is contained in the purified thionin. The purpose of using EDTA in Garcia-Olmedo et al. completely differs from that of the ion of copper of Lawyer et al. Accordingly, it is respectfully submitted that there is no reasonable motivation to combine the two references.

It is therefore respectfully submitted that applicants'

claimed invention is not rendered obvious over the references, either singly or combined in the manner relied upon in the Office Action, in view of the many distinctions discussed hereinabove. It is furthermore submitted that there are no teachings in the references to combine them in the manner relied upon in the Office Action.

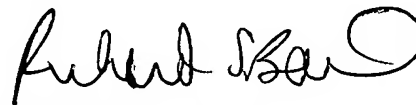
Reconsideration is requested. Allowance is solicited.

Enclosed is a check for \$18 in payment of one additional claim.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

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Respectfully submitted,



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Enclosure: Check for \$18.00